From: **Krishna Govindaraj** krishna@fdaregulatoryservice.com
Subject: RE: Non-Clinical Performance - GLP Pig Study
Date: March 14, 2019 at 7:07 PM
To: Angelia Inscoe angelia@collagenpin.com
Cc: chanda Gault chanda@collagenpin.com, Tray Rankin tray@cpinit.com, Tray Rankin tray@collagenpin.com

KG

Tray,

Here is the summary:

As originally proposed, the cost for non-clinical performance per non-GLP pig study was: Part 1,2&3: $49,196.43 (details at the end of this email).

If we are to request the non-clinical performance study in Pig Model per GLP. It would cost you an additional Euro 19,356.32 = USD 21,887.86 as testing cost.

Testing cost for GLP Pig Study = 71,084.29

30% consulting fee: $21,325.29

Total cost: $92,409.58

50% Payment required to start the testing: $46,204.79

Minus 50% Payment Received on Feb 28: - $33,981.45

Balance payment due NOW: $12,223.34 to start the GLP Pig Study
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Remaining balance of 50% - $46,204.79 due upon completion of the Pig study and issue of draft test report.

Please confirm, if we are good to go with this estimate. I will work with the testing lab to finalize the Pig study plan per GLP.

Thanks,
Krishna

From: Angelia Inscoe <angelia@collagenpin.com>
Sent: 28 February 2019 09:58
To: Krishna Govindaraj <krishna@fdaregulatoryservice.com>
Cc: chanda Gault <chanda@collagenpin.com>
Subject: Re: Checking in

I wired 33981.45 this morning.

Warm Regards,
Angelia Inscoe
Founder / C.E.O.
Collagen P.I.N. & Induction Therapies
The A method

423-754-6923 cell
502-909-2837 Office
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www.InductionTherapies.com
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On Feb 27, 2019, at 12:50 PM, Krishna Govindaraj <krishna@fdaregulatoryservice.com> wrote:

Hi Angelia,

I haven't included 30% as my consulting fee in the testing estimate, which is $14,958.80. If funds are available, please pay $7,379.40 (i.e 50%) as my consulting fee for this part of the work.

Thanks,
Krishna

From: Angelia Inscoe <angelia@collagenpin.com>
Sent: 27 February 2019 12:04
To: Krishna Govindaraj <Krishna@fdaregulatoryservice.com>
Subject: Re: Checking in

Process .... I will wire money tomorrow. Traveling today.

Warm Regards,
Angelia Inscoe, CEO
O 502-909-2837
Induction Therapies
Collagen P.I.N.
www.inductiontherapies.com

On Feb 27, 2019, at 11:59 AM, Krishna Govindaraj <Krishna@fdaregulatoryservice.com> wrote:

> Hi Angelia/Chanda,
>
> That amount seems to be correct. The 100% payment of

payment for Part 1 of the study is USD 4007.67 + 50% payment for Part 2 & 3 of the study is 22,594.38 = 26,602.05 is the total amount required to proceed with the pig study.

Please confirm, if you would like to proceed with this study.

Krishna

From: chanda Gault <chanda@collagenpin.com>
Sent: 27 February 2019 09:45
To: Krishna Govindaraj <krishna@fdaregulatoryservice.com>
Cc: chanda Gault <chanda@collagenpin.com>; Tray Rankin <tray@collagenpin.com>; Ali - ICE - ICE <angelia@collagenpin.com>
Subject: Re: Checking in

Hi Krishna,

I did a currency converter and it looks like this test totals 49196.42 in USD, and the initial payment would be 4007.67 USD. Is that correct?

Chanda Steinberg
In-House Counsel & Director of Human Resources
Collagen P.I.N. & Induction Therapies
3600 Chamberlain Lane
Unit 336
Louisville, KY 40241
877-746-4407
chanda@collagenpin.com

> On Feb 26, 2019, at 10:01 PM, Krishna Govindaraj <krishna@fdaregulatoryservice.com> wrote:
>
> Tray,
>
> Since I had difficulty calling from my US Phone, I tried calling you using Whatsapp yesterday and again twice this evening, but not able to reach you or Chanda.

I got an estimate from the Pig Study lab (for non-clinical performance testing of the device) for **Euro** 43,209.74 and this estimate is valid for 30 days. The lab hasn't included any Tax on the estimate that I got. I am going to check with them to make sure, if there would be tax, any other additional charges or this would be the fixed price to complete the proposed study. This is a Europe based GLP lab, but the price is for non-GLP study to protocol design, schedule, documentation, final report, animal cost, housing, veterinary care and facilities, protocol execution, delegated phases and externalized procedures, project management and quality assurance for both pilot study and actual study phases. If we want to do this study under GLP conditions, the cost would be higher. The FDA would ok with non-GLP study for a non-clinical performance test. Most likely this should be the lab that did the pig study for the German Exceed microneedling device.

This is for performing the study on One test item (12 PIN or 36 PIN), at max penetration depth and max speed (based on our internal discussion and also extensive discussion with the testing lab, I went for worst case scenario from the FDA's regulatory review and approval standpoint) based on the test parameters that we discussed earlier. The study would have three parts: 1. protocol design, schedule, documentation, ethical committee review and study authorization; 2. in vivo Pilot study (to standardize all the protocol and test procedures before performing the actual study) to assess on the skin areas to run the study with the microneedle device in pigs; 3. then perform the actual study, In vivo study to assess on the accuracy and safety of a microneedle device in pigs.

As mentioned above, this study would be done in three parts. Pat 1 of this study would cost about Euro 3,520.00 and 100% payment; Part 2 cost about Euro 6,698.66; and Part 3 cost about 32,991.08. Part 2 & 3, 50% payment to start the work and remaining 50% payment due upon issue of draft test report.

I wish we had another one or two competing pig study labs to negotiate the above price. If you want, I would keep looking for another lab, but it's going to take at least another month or more for me to search and get another competing quote, possibly for a lower price.

lower price.

Please let me know your thoughts and how you want to proceed in this regard. I would respond to the lab and proceed further only after getting your response.

Thanks,
Krishna

From: chanda Gault <chanda@collagenpin.com>
Sent: 22 February 2019 16:24
To: Krishna Govindaraj <Krishna@fdaregulatoryservice.com>
Cc: chanda Gault <chanda@collagenpin.com>; Tray Rankin <tray@collagenpin.com>; Ali - ICE - ICE <angelia@collagenpin.com>
Subject: Re: Checking in

Hi Krishna,

Did you receive the product you needed for the disinfection validation tests?

Also, I haven't had a chance to speak with Tray about the status of the pig testing, and I believe he responded to some questions that you had in connection with these tests. Can you tell me what the status of that is, and if you are waiting on anything else from us?

Thanks!

Chanda

Chanda Steinberg
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On Feb 15, 2019, at 1:12 AM, Krishna Govindaraj <Krishna@fdaregulatoryservice.com> wrote:

Tray,

As mentioned in my earlier email, I am in the process of ordering the reprocessing (cleaning & disinfection) validation tests. Please send 12 each for cleaning and disinfection validation tests, total of 24 devices. I you are going to ship it me, it has to reach me before Tuesday, Feb 19th for me to mail it to the concerned lab before my trip to India, Feb 20th. If not, I will provide you the address and you will take the responsibility to ship it directly to the testing lab.

These devices would be used, intentionally soiled with 5 pathogenic microorganisms, including Mycobacterium species that causes tuberculosis and tested for the reprocessing validation (for a device of intermediate level risk). If you specifically instruct the lab, it would be returned to you after the lab completes all the reprocessing val related testing. If not, the device would be disposed-off appropriately as a biohazard waste.

To answer your second question, there is balance of $27,111.50 to be paid to order the remaining tests. I will order the remaining tests, whenever I receive your next payment.

Thanks,
Krishna

From: Tray Rankin <tray@collagenpin.com>
Sent: 14 February 2019 16:24
To: Krishna Govindaraj

To: Krishna Govindaraj <krishna@fdaregulatoryservice.com>
Cc: chanda Gault <chanda@collagenpin.com>; Ali - ICE - ICE <angelia@collagenpin.com>
Subject: Re: Checking in

how many devices do you need for this (still 12), and how much to keep these tests moving forward??

> On Feb 12, 2019, at 6:49 PM, Krishna Govindaraj <krishna@fdaregulatoryservice.com> wrote:
>
> Tray,
>
> Reprocessing validation: Funds and required number of samples/devices to send it to the concerned testing lab. I already requested for the number of samples, but haven't got it yet. I would check the proposal and send it again tomorrow. If you can take care of this, I would try push this work before my trip.
>
> Additional Information: The reviewer usually (almost always) send a deficiency letter and request for additional information.
>
> Krishna
>
> ---
>
> **From:** Tray Rankin <tray@collagenpin.com>
> **Sent:** 12 February 2019 18:34
> **To:** Krishna Govindaraj <Krishna@fdaregulatoryserv

ice.com>
Cc: chanda Gault <chanda@collagenpin.com> ; Ali - ICE - ICE <angelia@collagenpin.com>
Subject: Re: Checking in

what is holding us up on the reprocessing validation testing, funds??

is there always a "request for additional information/deficiency response"?

On Feb 12, 2019, at 6:28 PM, Krishna Govindaraj <Krishna@fdaregulatoryservice.com> wrote:

Hi Chanda,

I could find only one large animal facility in India so far through my network, which is a multispecialty hospital and a Govt. of India Institution that has the capability to do the kind of non-clinical performance test facility that we are looking for. I spoke to one of

spoke to one of the scientist at this facility on Sun and again last night and plan to talk to the Director of the test facility tonight to see, if they would be willing to undertake our project work and give us a quote. I should know more only after I have an opportunity to talk to the person in-charge at this facility. I will to get back to you with further updates either tomorrow or Thur.

If they agree to take up this project, we will need a high speed camera. I am leaving to India on Wed, Feb 20th. If this camera is available, I would like to carry it along with me to see if I could get this work done during this trip. I know Tray had asked for some specs to buy this camera, but I haven't had a chance to work on it further. I will trv to do some

research on this and get back to you.

One of US lab in the Washington DC metro area that has large animal facility said, they wouldn't be interested in working on this kind of a project.

Once we submit our 510(k) to FDA, the process usually takes about 120 days to get a yes or no answer. Here is the break-up: The reviewer usually would request for additional information/deficiency response in 90 days. Once we submit the additional response, the FDA would/can make a final decision in about 30 days. The entire process of 510(k) clearance may take between 120-180 days, depending on how fast we respond to FDA's request for additional response.

for Reprocessing validation testing: Two of the US labs that quoted for this test contacted me to know the status, because there seems to be a que and wait period. I believe once we order this test, it takes about 8-12 weeks to get the test report. Do you have any idea as to when we would be ready to start this work. If possible, I would prefer to get this testing work started before my trip to India.

Thanks,
Krishna

From: chanda Gault <chanda@collagenpin.com>
Sent: 12 February 2019 09:28
To: Krishna Govindaraj <krishna@fdaregulatoryservice.com>
Cc: chanda Gault <chanda@collagenpin.com>; Tray Rankin <tray@collagenpin.com>; Angelia Inscoe

<angelia@collagenpin.com>
Subject: Checking in

Hi Krishna,

I wanted to check with you on the status of finding a lab that can perform the pig testing. Have you found anyone who has this capability to give us a quote?

Also, once we are able to file the submission with the FDA, do you know how long that review process generally takes? Assuming that they don't request additional information?

Thank you!

Chanda

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